Traditional 510(k) SUMMARY

This Summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21CFR §807.92

The assigned 510(K) number is : K091229 JUL 31 2009

A. 510(K) number is :

B. Purpose for Submission:
New submission for an accessory Data Management Software application for glucose meters

C. Submitter information

Company: EPS Bio Technology Corp.
Address: 2F, No. 49-2, Lane 2, Guang Fu Rd., Sec.2 Hsinchu City, Taiwan, R.O.C.
Contact Name: Mr. Y.C. Lei, General Manager
Phone: 886-3-5752522
Fax: 886-3-5752552

D. Proprietary and Established Names:
GlucoManager Data Management Software

D. Type of Test:
GlucoManager Data Management Software is a software medical device which serves as RS232 cable based accessory which interfaces between the software in personal glucose monitoring devices and the GlucoManager Data Management Software.

E. System Descriptions:

1. Device Description:
The GlucoManager Data Management Software enable users the ability to export data from the EasyMax N (k083099) glucose meter to a computer via a RS232 Cable. The GlucoManager Data Management Software enable users in review, analysis and evaluation of historical blood glucose test results to support effective diabetes management. The device is not intended to provide any diagnosis based upon patient results.

2. Principles of Operation:
The GlucoManager Data Management Software has an interface accessory to compatible meters: EasyMax N (k083099) meter.

3. Modes of Operation:

The GlucoManager Data Management Software is compatible with Microsoft® Windows® Vesta, XP, Windows 2000, Windows 98,Windows Me operating systems

Hardware specifications:

- Intel(or Compatible) Pentium II 300 MHz processor or higher
- 32 Megabytes (MB) or greater of available random access memory (RAM)
- 20 MB of free hard disk space minimum
- Compact disk (CD) drive
- Mouse
- 800 x 600 (or higher) resolution monitor
- EPS RS232 Download Cable

F. Common or Usual Name:
GlucoManager Data Management Software

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1345, Glucose Test System
   21CFR Sec.-862.2100 - Calculator/data processing module for clinical use.

2. Classification:
   Class II and 1 respectively

3. Product code:
   NBW, System Test, Blood Glucose, Over the Counter
   JQP, Calculator/Data Processing Module, For Clinical Use

4. Panel:
   Chemistry 75

H. Intended Use:

1. Intended use(s):
   see Indications for Use below

2. Indication(s) for use:

   The GlucoManager Data Management Software (GDMS) is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation blood glucose test results to support effective diabetes management. The device is not intended to provide any diagnosis based upon patient results.

3. Special conditions for use statement(s):
   Compatible meters: EasyMax N (k083099) meter

4. Special instrument requirements:
Not Applicable

I. Substantial Equivalence Information:

1. Predicate device name(s):
In Touch Diabetes Management Software

2. Device Company
Lifescan

3. Predicate 510(k) number(s):
k984527

4. Comparison with predicate:

4.1 Similarities

Element of Comparison	LifeScan IN TOUCH® Diabetes Management Software (k984527)	EPS GlucoManager Data Management Software (GDMS)
About User		
- Intended Use (S)	IN TOUCH® Diabetes Management Software can help healthcare professionals and people with diabetes monitor blood glucose levels. You and your healthcare professional can use IN TOUCH Software to plan meals, exercise, lifestyle, and medication to help control diabetes. IN TOUCH Diabetes Management Software lets you track and review blood glucose test results. This helps you keep your blood glucose levels stable.	The GlucoManager Data Management Software (GDMS) is intended for use in home and clinical settings to aid people with diabetes and their health care professionals in the review, analysis and evaluation blood glucose test results to support effective diabetes management. The device is not intended to provide any diagnosis based upon patient results.
- Single User Use	Single and Multi-Patient	Single Patient
About Installation		
- Computer System Requirement	* A supported blood glucose meter, * CD-Rom drive * 100~200 MB minimum of free hard disk space while installation, 100 MB after installation * 128 MB minimum of free RAM,	* EasyMax N Blood Glucose Meter, * Compact Disk (CD) drive * 20 MB or greater of free hard disk space, * 32 MB or greater of free RAM,

	* Video monitor and adapter with at least 800 x 600 pixels and 256 colors, * Available 9-pin or 25-pin COM or USB port. * Operating system of Microsoft® Windows® 98, Windows® 2000 Professional, Windows® XP Home and Professional	* 800 x 600 (or higher) resolution monitor, * Available 9-pin RS232 serial port. * Operating system of Microsoft® Windows® Me, Windows 98, Windows® 2000, Windows® XP, Windows® Vista
- Installation of Program	Installed using CD	Installed using CD
- Language Capabilities	English, Spanish	English
- Ability to Uninstall Program	Yes	Yes
- Ability to Link to Different Database Versions	Yes	Yes
- Technical Support	Yes	Yes, Customer Service Center Toll-Free Number: 1-866-203-2761
About Transmission		
- Auto-detect COM Port	Yes	Yes
- Cable Availability	Serial Cable, Cable available separately.	Serial Cable, Cable available separately.
- Capable of Uploading Data from Various Devices	Software driver must be uploaded on the device or installed on PC.	Software driver must be uploaded on the device or installed on PC.
About Operation		
- Ability to Access Program via Icon or Explorer	Yes	Yes
- Viewing the User's Manual	Yes, link provided via icon	Yes
- Copy Database to Separate File	Yes	Yes
- Copy Saved Database Back to Achieve Database	Yes	Yes
About Personal Settings		
- Unit of Blood Glucose	Choice of mg/dL or mmol/L	Pre-Set to mg/dL
About Report		
- Report Types	Logbook, Line Graph, Average Readings.	Log Book, Glucose Trend, Average Day, Average Week
About Modifying Results		

- Downloaded Results Cannot Be Edited or Deleted	Yes	Yes
- Ability to Modify Meter Average Results	No	No
About Patient and Therapy Management		
- Required Information on Use (Patient) Enter	No required information	No use (patient) enter

4. 2 Differences

Element of Comparison	**LifeScan IN TOUCH® Diabetes Management Software (k984527)**	**EPS GlucoManager Data Management Software (GDMS)**
About Operation		
- Ability to Clear Meter Results in Memory and Set Mater Clock to a Specific Date and Time	Yes	No
- Ability to Email Report from PC Directly from Program	Yes	No
About Personal Settings		
- Ability to Display 12 or 24 Hour Clock Format and Change Date Format	Yes, mm/dd/yy or dd/mm/yy.	No
- Ability to Synchronize Meter Clock to PC Upon Download	Yes	No
- Ability to Personalize Target Ranges	Yes	No
- Ability to Set Default Target Range	Yes	No
- Ability to Enter Hypoglycemic Range	Yes	No
- Ability to Enter Insulin Regiment	Yes	No
- Ability to Set Default Favorite Report	Yes	No
- Ability to Default to	Yes	No

Manufacturer Settings		
About Report		
- Report Types	Data List, Data Statistics, Within Target, Standard Day, Histogram Chart, 14 Days Summary, Glucose & Insulin	No
About Modifying Results		
- Manual Entry	Yes	No
- Ability to Input Additional Information	Yes, insulin doses, carb data, exercise data, health notes, comments.	No
- Ability to Specify Complications Associated with Diabetes by Patient	Yes	No
- Specifying / Entering Medications / Insulin	Yes, up to three different medicines, insulin types	No
- Deleting Results, Patients and All Accompanying Records	Yes, only manual entry results may be deleted.	No
About Patient and Therapy Management		
- Search Patient Capability	Yes	No
- Diabetes Control	Yes, including insulin list, exercise, carbohydrate	No
- Doctor Information and Diabetes Educator Information	Yes, one doctor may be entered. one diabetes educator may be entered.	No
- Ability to Limit Result Selection by Last Transfer	Yes, with the exception of the In TOUCH Ultra.	No

J. Standard/Guidance Document Referenced (if applicable):

1. IEC 62304:2006 Medical device software – Software life cycle process
2. ISO 14971:2007, Medical Devices – Application of Risk Management to Medical Devices

K. Test Principle:

Not Applicable

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
   a. Precision/Reproducibility:
      See compatible meters EasyMax N SMBG system (k083099)
   b. Linearity/assay reportable range:
      See compatible meters EasyMax N SMBG system (k083099)
   c. Traceability, Stability, Expected values (controls, calibrators, or methods):
      See compatible meters EasyMax N SMBG system (k083099)
   d. Detection limit:
      See compatible meters EasyMax N SMBG system (k083099)
   e. Analytical specificity:
      See compatible meters EasyMax N SMBG system (k083099)
   f. Assay cut-off:
      See compatible meters EasyMax N SMBG system (k083099)

2. Comparison studies:
   a. Method comparison with predicate device:
      See compatible meters EasyMax N SMBG system (k083099)
   b. Matrix comparison:
      See compatible meters EasyMax N SMBG system (k083099)

3. Clinical studies:
   a. Clinical Sensitivity:
      See compatible meters EasyMax N SMBG system (k083099)
   b. Clinical specificity:
      See compatible meters EasyMax N SMBG system (k083099)
   c. Other clinical supportive data (when a. and b. are not applicable):
      A User acceptance Study using 106 subjects was conducted to evaluate the GlucoManager Data Management Software with the following objectives:

      1. To evaluate design and ease-of-use
      2. To document participant feedback on the features / functions
      3. To document Observer feedback on participant performance
      4. To validate the user instructions are accurate and easy to follow
      5. To evaluate participant ratings with respect to features / functions
      6. To report any discrepancies (bugs/error messages) found during the evaluation

The subjects (Users) were required to have a minimum of basic computer skills and feel comfortable using a Windows-based Operating System.

Conclusions were based on the subjects' ability to demonstrate by usage and evaluation (rating) of features/functions (recorded as responses to 19 feature/function tests), their understanding of the applications of the software, their understanding of how to use the software, their comprehension of the contents of the instructions for use, as well as user assessment of ease-of-use based on a separate questionnaire.

Performance of each User was recorded and evaluated by EPS study administrators (Observers), who are familiar with proper use of GlucoManager Data Management Software. Observers rated each subject's performance using four general questions.

4. Clinical cut-off:
   See above associated devices

5. Expected values/Reference range:
   See above associated devices

M. Proposed Labeling:
The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

N. Conclusion:
The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

EPS Bio Technology Corp.
c/o Y.C. Lei
2 F, No.49-2, Lane 2, Sec. 2, Guang Fu Road
Hsinchu City
China (Taiwan) 300

JUL 31 2009

Re: k091229
Trade/Device Name: Glucomanager Data Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system.
Regulatory Class: II
Product Code: NBW, JQP
Dated: April 23, 2009
Received: May 05, 2009

Dear: Y.C. Lei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091229

Device Name: GlucoManager Data Management Software

Indications for Use:

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Prescription Use ___V___ AND/OR Over-The-Counter Use ___V___

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K091229